CHILDRENS ALLERGY RELIEF- diphenhydramine hydrochloride liquid
AptaPharma Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredient

Drug Facts

Active ingredient
(in each 5 mL teaspoon)

Diphenhydramine HCL 12.5 mg

Purpose

Antihistamine

Keep out of reach of children

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Uses

- temporarily relieves these symptoms due to hay fever or other respiratory allergies:
  - sneezing
  - itching of the nose or throat
  - runny nose
  - itchy watery eyes
- temporarily relieves these symptoms due to the common cold:
  - sneezing
  - runny nose

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin
- to make a child sleepy

Ask a doctor before use if the child has

- glaucoma
- a breathing problem such as chronic bronchitis

Ask a doctor or pharmacist before use if the child is

taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- excitability may occur, especially in children
- sedatives and tranquilizers may increase drowsiness

Directions

- if needed, take every 4-6 hours
- do not take more than 6 doses in 24 hours

Children under 4 years of age:	do not use
Children 4 to under 6 years of age:	do not use unless directed by a doctor
Children 6 to under 12 years of age:	1 to 2 teaspoonfuls (12.5 mg to 25 mg)

Other information

- **Keep carton for full directions for use**
- each teaspoonful contains: sodium 10 mg
- store at 20-25 ° C (68-77 ° F)
- dosage cup provided

Inactive ingredients

Citric acid, D and C Red # 33, FD and C Red # 40, flavor, glycerin, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose

Questions or comments?

Call weekdays from 9:30 AM to 4:30 PM EST at

1-877-798-5944

Product Label

SOUND BODY™
COMPARE TO THE ACTIVE INGREDIENT IN CHILDREN'S BENADRYL® ALLERGY LIQUID*

Relieves: Sneezing, Runny Nose, Itchy Watery Eyes, Itchy Throat

Children's
Allergy
Relief

Diphenhydramine HCL Oral Solution Antihistamine

Alcohol-free

Cherry Flavor

4 FL OZ (118 mL)

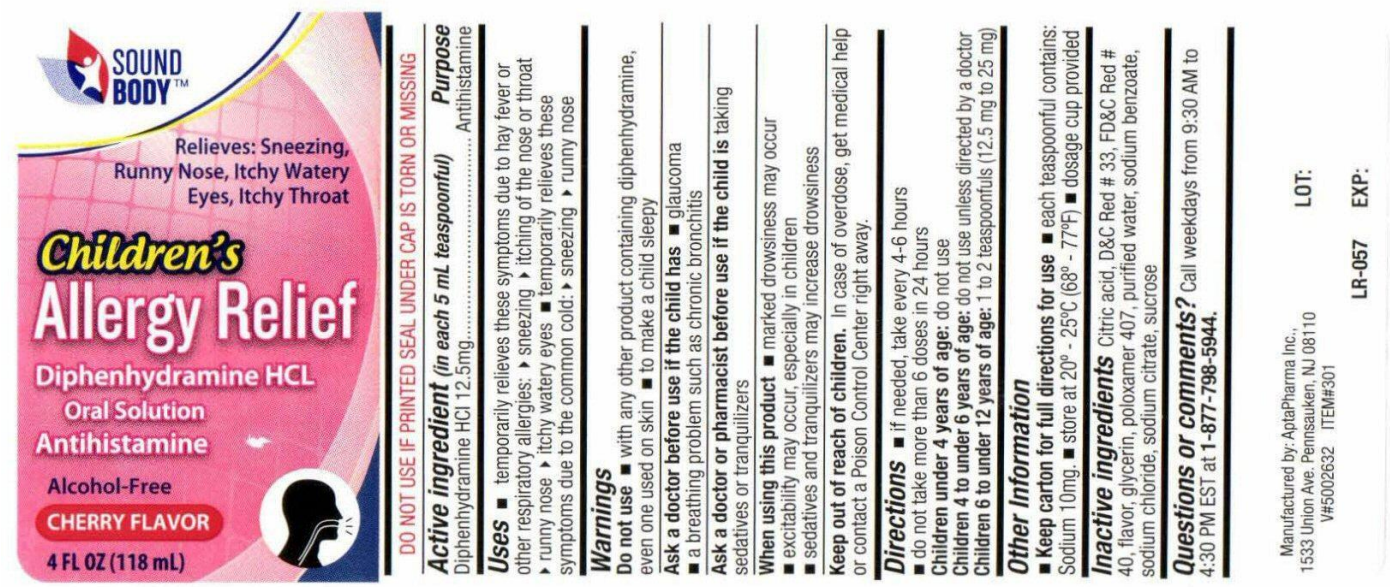
DO NOT USE IF PRINTED SEAL UNDER CAP IS TORN OR MISSING

Manufactured by:
AptaPharma Inc.
1533 Union Ave.
Pennsauken, NJ 08110

V#5002632 ITEM#301

BX-034

LOT:
EXP:



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CHILDRENS ALLERGY RELIEF

diphenhydramine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76281-301
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color		**Score**	

Shape		**Size**	
Flavor	CHERRY (CHERRY)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76281-301-24	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/21/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/21/2013	

Labeler - AptaPharma Inc. (790523323)

Registrant - AptaPharma Inc. (790523323)

Establishment

Name	Address	ID/FEI	Business Operations
AptaPharma Inc.		790523323	manufacture(76281-301)

Revised: 10/2019 AptaPharma Inc.